The Office of Fair Trading report: a prescription for value-based drug pricing

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According to the recent independent report from the Office of Fair Trading (OFT), the government's financial watchdog, the UK system for regulating drug prices has failed to deliver cost effective medicines for the National Health Service. Although the UK market only accounts for 3.45% of global pharmaceutical sales, it is thought that it can affect 25% of global demand as there are many countries that set their prices by reference to the UK. UK prescription drug expenditure amounts to approximately £11 billion per annum, of which approximately £8 billion is spent on branded, on-patent medications. The potential for reform of the UK pricing mechanism to produce much larger gains through driving investment in areas of clinical need is considerable.

The focus of the report is on improving the value that the pricing system can deliver, and the criticisms within the report are directed toward the current pharmaceutical pricing structure[1] and not at the pharmaceutical industry. With the link broken between who benefits and who pays, and with both the cost and benefit sides of the decision making process either unknown or complex, the OFT argue for centralized assessment analogous to that performed in specific selected fields by NICE, avoiding the need for regional assessments and 'reinventing the wheel' in different parts of the country. This would not only result in some savings from price reductions for some drugs, but also increases for others and overall gains in the health outcomes produced by the more effective budget allocation.

Much of the criticism detailed within the report is not new. The OFT estimates that potential savings of approximately £500 million per annum could have been realized through introducing its raft of reforms in 2005. This is largely attributable to the current disparity in the price of statins, which it estimates would produce £375 million pounds of the total saving if a price readjustment were to occur in line with simvastatin. The savings from generic substitution have previously been reported,[2–5] while the distortions introduced by current incentives to exploit cost structures that reward increasing sales beyond the justifiable therapeutic market have also been recently highlighted.[6]

In considering the use of medicines in the NHS within a 'supply and demand' model, the OFT identified peculiarities on the demand side. Medicines are unlike other areas of consumer purchases because there is considerable distance between the decision maker (typically the doctor with the patient) and the payer for the medicine (the NHS). Choosing the best medicine for a patient involves an analysis of both cost and benefit. The information and analyses required to make an informed decision on benefit is esoteric. For costs, the OFT showed in a study involving 1000 UK general practitioners (GPs) that they had they had a 'weak knowledge of the prices of some of the most widely prescribed drugs in the UK.' The agency also observed that patients are relatively insensitive to medication costs, as their contribution to expenditure on prescription pharmaceuticals amounts to less than 5%—a lower rate than almost all other countries in the world except the Netherlands. The context of these findings are important; the report acknowledges that levels of generic prescribing are high by European and North American levels and uptake of new drugs is relatively slow compared to other countries.

The current regulatory scheme for drug prices in the UK, the Prescription Drug Pricing Regulation Scheme (PPRS), has been in operation in various forms since 1957 and has been criticized as anachronistic and in need of reform.[7] The scheme operates through a system of profit caps and price controls that are negotiated between manufacturers and the Department of Health. It has therefore not been designed to improve the efficiency of the health service at an operational level but has instead served to retrospectively regulate its excesses and shortcomings, and the report finds it to be unsuited for an innovative sector such as pharmaceuticals. For example, the profit claw back system fails, as it returns only 0.01% of costs to the NHS. Recent initiatives to promote generic prescribing could be undermined by the PPRS scheme, as the potential exists for manufacturers to negotiate refunds if their profits fall below expected levels. A further problem is that recent price cuts of 7% across the board took no account of the value of medicines to patients. These are

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issues for pharmaceutical companies, health care payers and patients alike. The PPRS has also been criticized for its lack of transparency about the profit cap and price setting discussions that are undertaken.

The OFT report confirms these previous criticisms and goes further. It notes the current system's lack of incentives for manufacturers to offer value-based products and for them to be appropriately rewarded for innovation. The report notes that the number of new molecular entities (NMEs) registered globally has fallen dramatically from its peak of around 50 per year in the 1990s to around 35 per year over the last few years; there is therefore reasonable cause to seriously consider any new proposals that may stimulate increased innovation. The current system sets maximum and minimum levels of profit and therefore reduces the incentive for companies to produce innovative new drugs, which is not in the longer term interests of either pharmaceutical companies or patients. The report does not find merit in the valuation of 'innovation in itself' (i.e. innovation that does not provide value over currently available effective medications).

The report does not favour a categorization of 'me-too' or 'innovative' drugs due to the incremental gains seen with a succession of drugs. This concept is well illustrated with beta-blockers, with significant pharmacological differences between early and later agents resulting in therapeutically useful differences across the class. Similar but less compelling arguments can be made in relation to statins or antihistamines. The extent to which this is generally true is likely to be variable, and there is undoubtedly considerable expenditure incurred in producing some individual drugs within a class that offer little significant incremental benefits (e.g. the nine drugs that comprise ACE inhibitors).

As patients' advocates, doctors should embrace the reforms in this report. There will be considerable pressure to stem its recommendations, most notably from the pharmaceutical industry. The reforms have been formulated with recognition of the need for a sensitive approach to implementation that relies on maintaining the confidence of all stakeholders. The report identifies several solutions that include modifications to the current system or the extension of the role of Primary Care Organizations (PCOs), both options that the OFT believes are not currently feasible. The key proposals are for the introduction of solutions to address drug pricing either before or later after drug launch, when more data is available. Both strategies would require value-based pricing to evaluate the incremental value of new drugs in relation to pre-existing members of the class. The report rejects an argument from the pharmaceutical industry that this process would delay launch and defer access to new drugs for patients in need after international enquiries indicate that most countries already used such an approach, with the exception of the UK and Germany.

The OFT report has looked in reasonable detail at the technical aspects of making value-based assessments, including consideration of the merits of quality-adjusted life years (QALYs) and the use of the 'current best standard of care' as conventional comparator for Health Technology Appraisal (HTA). In-depth issues—such as the arguments for not appraising patent drugs versus off-patent drugs—have been examined (and dismissed). The report identifies and recommends current bodies such as the UK's National Institute for Health and Clinical Excellence (NICE) to undertake value-based assessments after conducting international enquiries that indicate that NICE is regarded as a gold standard and world-class body in the field of HTA. A previous independent and external assessment conducted by the World Health Organization came to similar conclusions around NICE's proficiency in HTA.[8] The OFT report's approach to analysing the 'decision problem' formulation in HTA validates the current NICE methodology with reference to a financial markets framework perspective.

If implemented, this report would represent a significant and logical extension to NICE's current powers. The current situation, where drugs may be rejected on the basis of cost-effectiveness, effectively implies a price ceiling in relation to the particular effectiveness of a specific drug beyond which the drug is deemed too expensive. NICE has not previously been remitted to define the actual price it would be willing to pay for a technology to be reimbursed by the NHS, and modification to its remit could ensure greater access to medicines for patients and reduce much of the controversy surrounding some of its decisions to restrict certain drugs. This is particularly true due to the striking failure of professional and patient groups to lobby drug manufacturers to reduce their prices to levels that represent acceptable value to the NHS.

Introduction of value-based pricing would not be sufficient to ensure appropriate use of medicines in the correct clinical subgroups in practice. To address this aspect of drug pricing, the report advocates a fixed-budget approach that would result in appropriate downward price reduction for medicines with recognition of their incremental value (i.e. value-driven competition).

The potential savings identified through reform of the PPRS scheme, around £500 million in 2005, are high in absolute terms but should also be regarded in context; they represent 6.25% of the on-patent drug budget and 4.5% of the overall drug budget (i.e. including generic medications). The cost of implementing the OFT recommendations relate largely to increased resources for HTA to enable price setting—an additional £6 million over current expenditure. Clearly, this would be a highly cost-effective exercise regardless of the considerable intangible benefits, such as

optimization of health gains and the increased stimulus for innovation.

The OFT report is comprehensive, penetrating and bold. If implemented, the recommendations will improve the efficiency of the tax-funded market for pharmaceutical products in the UK whilst simultaneously stimulating innovation and harnessing the transparency of the NICE decision making process. As it has been suggested that pharmaceutical companies may withdraw research and development activities in response to attempts to secure cost effectiveness,[9] it is notable that the report questions the belief that the current pricing framework is a valuable pillar of UK industrial policy that links pharmaceutical research and development with decisions by pharmaceutical companies to invest in the UK. This should be contrasted with the conclusion of the joint industry and government 'Pharmaceutical Industry Competitive Task Force'[10] that the freedom to set launch prices may affect companies' investments in the UK. Countries such as Ireland that have lower spending on pharmaceuticals and have been successful in attracting inward investment illustrate that the ultimate goal of industrial policy should be to develop a large, well-trained workforce in an attractive business environment that does not depend on indirect subsidies. Whether UK government ministers endorse the findings from the independent OFT report, which they can choose to ignore if minded, will be key.

The UK government has 120 days to respond to this report, although the proposed reforms if accepted in entirety would not take effect until 2010. These recommendations should be considered as constituting serious and radical reforms that would deliver value-based and effective price reimbursement systems that would benefit patients and reward manufacturers appropriately while naturally extending the innovative role of health technology evaluation in UK.

Competing interests Rubin Minhas is a Technology Appraisal Committee member within NICE and a participant within several NICE guidelines groups. James C Moon has received lecture honoraria from MSD and Sanofi-Aventis, and management training from Pfizer. The views represented are those of the authors and not of any affiliated organizations.

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